DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

M30091

September 23, 1999

WARNING LETTER

cc: HFI-35
DWA

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99-56

Kevin M. Patterson
Director of Distribution
Fleming Companies, Inc.
3501 Marshall Street NE
Minneapolis, MN 55440

Dear Mr. Patterson:

The Food and Drug Administration (FDA) conducted an inspection of your multiple food storage facility on July 30, 1999, to determine your compliance with the Seafood HACCP and GMP regulations denoted in Title 21, Code of Federal Regulations, Parts 123 and 110, respectively (21 CFR 123 And 110). At the conclusion of this inspection the FDA investigator issued a list of inspectional observations on the form FDA-483 and discussed them with you.

Your firm is in violation of 21 CFR 123.9 (c) because during our investigation on July 29-30, 1999, your firm could not show our investigator its HACCP plan and monitoring records for the storage of ready-to-eat seafood products. These regulations require seafood processors to make all records, plans, and procedures available for official review by the FDA during inspection

We have determined that you must have and implement a HACCP plan for the control of pathogen growth during the storage of your ready-to-eat seafood salads. At a minimum, such a plan must set a critical limit for cooler temperatures to reduce the likelihood of pathogen growth to an acceptable level and provide for monitoring of cooler temperature, record keeping of cooler temperatures and verification that your HACCP plan is working.

The listing of these inspectional observations is not intended to be an all-inclusive listing of the violations at your facility. As the most responsible individual at your facility, you are responsible to ensure your operations are in compliance with both local and federal requirements. These findings cause the seafood products manufactured at your facility to be adulterated according to Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) in that they

were manufactured and held under conditions whereby they may have been rendered injurious to health. The adulteration of a previously unadulterated food after shipment in interstate commerce and the shipment of an adulterated food in interstate commerce is prohibited by Section 301 of the Act.

Within 15 working days of receipt of this letter please provide a written response detailing the actions you have taken to correct these violations and prevent their recurrence. Also, include a timeline as to the projected completion dates for these corrective actions, so we may re-inspect to verify the effectiveness of your corrective action plan.

If you fail to take timely corrective actions, FDA may initiate legal actions against you and/or your products in the form of an injunction or seizure.

Your response and any questions you may have regarding this matter may be directed to Compliance Officer Thomas P. Nelson at the address indicated on the letterhead, or (612) 334-4100 ext: 177.

Sincerely,

Thomas P. Nelson
Acting Director
Minneapolis District

TPN./rfk